

AUG 20 2001

# MAINE STANDARDS COMPANY, LLC

## 510(k) SUMMARY

"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92."

"The assigned 510(k) number is: K012120."

Submitter: Maine Standards Company  
Address: 765 Roosevelt Trail  
Windham, ME 04062  
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Contact: Christine Beach, Mgr. RA/QA

Summary prepared on: June 29, 2001

Proprietary Name: VALIDATE Chem 4 Calibration Verification Test Set  
Common Name: Calibration Verification  
Classification Name: Calibrator, Multi-Analyte

### Predicate Devices:

1. **DOCUMENT** Enzyme Linearity Test Set, K932458, manufactured by CASCO NERL Diagnostics.
2. **DOCUMENT** Total/Direct Bilirubin Test Set, K924493, manufactured by CASCO NERL Diagnostics.
3. **Lipase LIN-TROL**, K863751, manufactured by Sigma Diagnostics, Inc.

**Device description:** VALIDATE Chem 4 Calibration Verification Test Set contains purified enzymes in a solution of bovine albumin stabilized with ethylene glycol. Multiple levels are provided to establish the relationship between theoretical operation and actual performance of each of the included analytes. Each set contains six (6) levels, including zero. Each bottle contains 5 milliliters.

**Intended use:** VALIDATE Chem 4 Calibration Verification Test Set is intended for *in vitro* diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems for the following analytes: alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, creatine kinase, gamma-glutamyl transferase, lactate dehydrogenase, lipase, total bilirubin, and direct bilirubin.

**Comparison to Predicate Devices:**

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	<b>VALIDATE CHEM 4 Calibration Verification Test Set</b>	<b>DOCUMENT Enzyme Linearity Test Set</b>	<b>DOCUMENT Total/Direct Bilirubin Test Set</b>	<b>Sigma Lipase Lin-Trol</b>
<b>Catalog #</b>	10004	E-100	M-107	L 1401
<b>Intended Use</b>	For <i>in vitro</i> diagnostic use in quantitatively verifying calibration, validating reportable ranges, and determining linearity in automated, semi-automated and manual chemistry systems.	For <i>in vitro</i> diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For <i>in vitro</i> diagnostic use in the quantitative determination of linearity in manual, automated and semi-automated chemistry systems.	For estimating the limits of linearity and/or calibration verification of reagent/instrument systems.
<b>Analytes</b>	ALT, AST, CK, LD, ALP, AMY, LIP, GGT, Total Bilirubin, and Direct Bilirubin	ALT, AST, CK, LD, ALP, AMY, GGT	Total Bilirubin Direct Bilirubin	Lipase
<b>Matrix</b>	Bovine Serum Albumin stabilized with Ethylene Glycol	Bovine Serum Albumin stabilized with Ethylene Glycol	Human Serum Albumin	Human Serum Base with Porcine Lipase
<b>Number of Levels</b>	6 including Zero	8 including Zero	5	1 Preparation with various dilutions
<b>Preparation</b>	Liquid, ready to use	Liquid, ready to use	Liquid, ready to use	Lyophilized
<b>Packaging</b>	5.0 mL each level	5.0 mL each level	4.0 mL each level	3 mL freeze dried concentrate
<b>Stability</b>	Until Expiration	Until Expiration	Until Expiration	Until Expiration
<b>Storage</b>	-10 to -20° C.	-10 to -20° C.	-10 to -20° C.	2- 4° C.

The performance of VALIDATE Chem 4 Calibration Verification Test Set solutions on the Roche Diagnostics Hitachi 911 instrument system as compared to DOCUMENT Enzyme Linearity Test Set, DOCUMENT Total/Direct Bilirubin Test Set, and Sigma Diagnostics Lipase LIN-TROL has been shown to be substantially equivalent using pre-production lots of VALIDATE Chem 4 Calibration Verification Test Set. The results of correlation comparisons between the VALIDATE Chem 4 Calibration Verification Test Set and the predicate devices are presented in Table 2.

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Table 2. Linear Regression Statistical Comparison between VALIDATE Chem 4 Calibration Verification Test Set and the predicate devices.

Analyte	VALIDATE Chem 4 Calibration Verification Test Set		DOCUMENT Enzyme Linearity Test Set		DOCUMENT Total/Direct Bilirubin Test Set		Sigma Diagnostics Lipase LIN-TROL	
	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)	Correlation Coefficient (r)	Regression Equation Y=intercept + slope(X)
ALT	0.999945	6.121 + .928	1.00000	-.141 + .996	N/A	N/A	N/A	N/A
AST	0.99964	4.351 + .949	0.99992	-4.055 + 1.022	N/A	N/A	N/A	N/A
GGT	0.99995	-.026 + .989	0.99997	-2.83 + 1.006	N/A	N/A	N/A	N/A
CK	0.99113	-8.94 + .937	0.99992	10.354 + .951	N/A	N/A	N/A	N/A
LD	0.99971	8.228 + .953	0.99988	3.402 + .954	N/A	N/A	N/A	N/A
ALP	0.99999	-1.285 + 1.001	0.99999	-.59 + 1.001	N/A	N/A	N/A	N/A
AMY	0.99998	-3.311 + 1.003	0.99979	27.07 + .945	N/A	N/A	N/A	N/A
LIP	0.99879	-1.399 + .965	N/A	N/A	N/A	N/A	0.99935	6.885 + 1.001
T. BILI	0.99956	.236 + .952	N/A	N/A	1.00000	.02 + .99X	N/A	N/A
D.BILI	0.99627	.477 + .86	N/A	N/A	0.99999	.027 + 1.018	N/A	N/A

### Summary:

Linear regression analysis was carried out on recovered values for each analyte and the VALIDATE Chem 4 Calibration Verification Test Set has been shown to be functionally equivalent for calibration verification and linearity assessment to DOCUMENT Enzyme Linearity Test Set, DOCUMENT Total/Direct Bilirubin Test Set, and Sigma Diagnostics Lipase LIN-TROL.



DEPARTMENT OF HEALTH & HUMAN SERVICES

AUG 20 2001

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Christine V. Beach  
Manager, RA/QA  
Maine Standards Company, LLC  
765 Roosevelt Trail  
Windham, ME 04062

Re: 510(k) Number: K012120  
Trade/Device Name: VALIDATE Chem 4 Calibration Verification Test Set  
Regulation Number: 862.1660  
Regulatory Class: Class I, Reserved  
Product Code: JJY  
Dated: July 3, 2001  
Received: July 6, 2001

Dear Ms. Beach:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

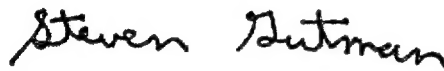
A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## INDICATIONS FOR USE STATEMENT

510(k) Number: K012120

Device Name: VALIDATE Chem 4 Calibration Verification Test Set

### Indications for Use:

The VALIDATE Chem 4 Calibration Verification Test Set is used by trained laboratory professionals for quantitatively verifying calibration, validating reportable ranges, and determining linearity of automated, semi-automated and manual chemistry systems for the following analytes: alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, creatine kinase, gamma-glutamyl transferase, lactate dehydrogenase, lipase, total bilirubin and direct bilirubin .

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### Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use  
(Per 21 CFR 801.109)

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*Keria Alexander for Jan Cooper*  
(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K012120